PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In Re Application of:	Lixiao Wang et al
Application No.:	08/685,338
Filed:	July 23, 1996
For:	HIGH COMPLIANCE, HIGH STRENGTH CATHETER BALLOONS USEFUL FOR TREATMENT OF GASTROINTESTINAL LESIONS
Examiner:	Cris L. Rodriguez
Group Art Unit:	3734

Box AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-5902

SUPPLEMENTAL REPLY BRIEF IN RESPONSE TO EXAMINER'S SUPPLEMENTAL ANSWER

This Reply Brief is submitted in response to the Examiner's Supplemental Answer mailed March 16, 2001. The Examiner's points of argument in the "Grounds of Rejection" section of the Examiner's Supplemental Answer are addressed below by paragraph.

Rejection Under §102

(2)

Claim 11 was rejected under 35 U.S.C. §102(e) as being anticipated by Anderson et al. (USPN 5500180). It is asserted that Anderson et al. teaches the balloon as claimed, which has been made by a process *similar* to that of Appellant's. The rejection states that Anderson et

al. teaches heating and pressurizing a block copolymer at a first elevated temperature and pressure followed by annealing at a second temperature and pressure lower than the first. The Examiner points to examples 2 and 3 for support. It is finally asserted that, since the reactants reaction conditions, and properties of the Anderson et al. process are similar to that of the instant invention, it was held that the resultant product of Anderson et al. anticipates the instant product by process of claim 11.

The rejection fails because it still has not been shown that the end product would likely appear to be identical, as required in the Board's Decision (see page 3, lines 7-9). The process of steps of the claimed invention are clearly different from those of Anderson et al. Further, both processes claim that their respective steps have an effect on the structure of the resulting product. The fact that they have a step in common does not make them similar for purposes of anticipation. In the art of balloon formation small differences in resulting balloons have significance. A difference in one step can result in a markedly different balloon. The vast quantity of catheter balloon art attests to this.

Rejected claim 11 requires the step of "*forming a balloon...*, wherein a tubing...is radially expanded under a first elevated pressure at an elevated temperature to form the balloon at a *first diameter*,...and the method including the further step of *annealing* the balloon at a second elevated temperature *less* than the first elevated temperature and a second pressure less than the first elevated pressure *for a time sufficient to shrink the formed balloon to a second diameter less than the first diameter.*" Beyond the physical effects the annealing step inherently has on the structure of the balloon, the claim requires further physical characteristics from the annealing step, namely the shrinking of the balloon from the first diameter to the second diameter. It has not been shown that Anderson et al teaches the annealing/shrinking step as required by the claim.

The rejection uses examples 2-3 of Anderson et al. to supply support for the anticipation rejection. However, the step outlined in examples 2-3 is a catheter sterilization step, which is a further aspect of the Anderson et al. invention, and not the balloon forming and setting steps outlined in example 1, which are applicable to claim 11. Examples 2-3 illustrate the

sterilization process on balloons already made by the process of example 1 (col. 11, lines 56-57). At the point of sterilization, the balloon is formed, removed from the mold and affixed to a catheter (see col. 10, lines 7-9). Claim 11 addresses the manufacturing of the balloon. By arguing that the sterilization step of Anderson et al. provides anticipatory teachings, the Examiner has raised a new issue which, heretofore, has not been raised.

The process of claim 11 should be compared to the balloon formation steps of Anderson's Example 1, which discusses a pre-blow, as described in the first paragraph, a series of blow cycles to form the balloon, as described in the second paragraph and a heat set step, as described in paragraph three. The steps of the second and third paragraphs, that being the balloon forming and the heat set steps, are the steps which are applicable in the comparison.

As seen in paragraphs 1-2 of Anderson's example 1, the blowing and stretching step is done at 290 psi at a temperature of 90°-100° C. After three blow cycles, the original outer diameter (note the first diameter in claim 11) increases to 0.1181 inches (3 mm). In the next step for making the balloons outlined in paragraph 3 of example 1, the pressure is lowered to 190 psi (lower than the first pressure of 290 psi), but the temperature was *increased*, not decreased as required by claim 11, to 110°C. The resulting balloon had a diameter of 3 mm (col. 11, lines 47-48), which is the same as the first diameter of 0.1181 inches (3 mm). This is different from the requirement of claim 11, wherein the second diameter is less than the first.

When a proper comparison is done, as shown above, it cannot be asserted that the balloons taught in Anderson et al. appear identical to those of claim 11. As discussed in Applicant's Appeal Brief and Reply Brief, the claimed heat shrink step has distinct effects upon the final balloon and the heat set step of Anderson et al. has distinct effects upon the final balloon. It has not been shown for purposes of an anticipation rejection that the resulting balloons appear to be identical. The rejection bases its statement that the resulting balloons appear to be identical on the assertion that the two methods are so similar that they must be identical. It has been shown by the Applicant that this is not so and that their are differences in the methods and therefore the resulting balloons.

For arguments sake, even if the sterilization step were to be considered a balloon forming step which can be compared to the second step of claim 11, the balloons of Anderson et al. would still have differing physical characteristics from those of claim 11. It is important to note that the heat set step in Anderson et al. is critical to the invention's teachings. Anderson et al. claim that the heat set step accounts for specific beneficial physical characteristics. The reference does not teach the making of the balloons without the heat set step. Anderson et al. claims that the improved properties of its balloon result from the method or process it teaches to form the balloons (see abstract and col 6, lines 13-23 and lines 29-32). It is asserted in Anderson et al. that "[t]he balloons formed using the process...will have an overall advantageous combination of **physical** properties...superior to those exhibited by the "compliant" balloons currently available." The heat set step taught by Anderson et al. clearly is used to contribute to these physical properties. Therefore, even if the Board were to analogize the second step of claim 11 with the sterilization step of Anderson et al., the resulting balloons from claim 11 and the methods of Anderson et al. would still not be identical due to the requirement of the heat set step in Anderson, which as mentioned above, has a critical "locking" effect on the final parameters of the balloon. (See col. 8, lines 55-60. See also col. 9, line 53, through col. 10, line 9.)

Although the sterilization process is an important part of the Anderson et al. disclosure, it is not meant to alter the physical characteristics of the balloon, let alone shrink the balloon as required by claim 11. In fact, the sterilization process is performed at a low temperature so that it doesn't adversely affect the structure of the balloon which was locked in place by the heat set step, including dimensional stability. (See col. 7, lines 40-47.) Since the heat set step provides the balloon with temperature and dimensional stability, the subsequent sterilization cannot be considered to be a shrink step. (See col. 10, lines 21-27.)

As such, even if the catheter sterilization process were to be considered a balloon forming step comparable to the second step of claim 11, it has not been shown that the resulting balloons would appear to be identical. In the more proper comparison, as outlined above, Applicant has shown that the resulting balloons do not appear to be identical considering the

differences between the corresponding second steps and the asserted effects which they have on the physical characteristics of the balloon material. Therefore, the rejection should be overturned.

Rejections Under §103

(4)

Claims 12-17, 35-42, 44 and 45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson et al.

With respect to claims 12-17, in addition to the Applicant's Brief on Appeal arguments with regard to the rejections to these claims, Applicant further offers the above arguments directed toward Examiner's additional comments concerning the patentability of the subject matter of claim 11. Since the rejection to these claim depends on Examiner's arguments for the rejection of claim 11, these rejections, which are the subject of Issue II, should be likewise overturned.

Applicant proposes the cancellation of claims 35, 36 and 40-42 without prejudice. As such, they will not be discussed. Applicant retains the right to pursue these claims in a later continuation. It is requested that claims 43-46 be considered in independent form for the remaining issues.

With respect to claims 37-39, it is asserted in the rejection that Anderson et al. teaches the balloons as claimed having parameters such as: 1) operational pressures which the balloon can be safely inflated without bursting of at least 12 atm (examples 3 and 4 are cited), 2) a nominal diameter of 3 mm at a certain inflation pressure, and 3) a diameter growth disclosed at column 4, lines 59-65, over a range of 3-12 atm.

Outside the field of angioplasty, to which the balloons of Anderson et al apply, relatively high compliant, high strength materials are desirable for some balloons used on esophageal, pyloric, colonic and anastomotic catheters and scopes. Claims 37-39 target distinctly different types of balloons which are used for different purposes. Specifically they are of

different sizes for different applications. Since the size of the balloons affect wall strength and compliance, Anderson's focused teaching is not helpful. Note that the larger the balloon, the higher the wall strength must be to burst at a given pressure. Thus, the specified burst pressures are quite high for each claim.

Anderson et al. does not discuss at all the effects of its parameters on large balloons. The minimum size in claim 37 is 6 mm and the minimum size in claims 38-39 is 12 mm. Anderson et al. only discusses small balloons of approximately 3 mm. There are distinct differences between how the larger balloons react with regard to distensibility and burst strength. It is not just a matter of design choice. The parameters of the claims for the larger balloons are unique for their size. As mentioned in Applicant's prior briefs, the size of the balloons make them distinctly different in that they have differing applications and in that it is unique to have large balloons with high strength and compliance at the same time. The balloons of claims 38-39 are quite large (12mm or more) and have very different uses. Once again, they are distinct for their size and for the unique quality of maintaining a relatively high wall strength and compliance. As mentioned above, the size of the balloon distinctly affects the other parameters and to balance these parameters in the manner claimed is unique. No where in Anderson et al. are such balloons discussed.

It has not been sufficiently shown that Anderson teaches or suggests methods for providing this balance of characteristics. Moreover, nothing in Anderson et al. teaches or suggests a balloon of any type within the specified size range of 6-12 mm, not to mention the range of 12-30 mm. Therefore, Applicant respectfully submits that the rejection has been overcome and requests that the rejection be overruled.

Further, there is no indication or citing why the unique set of parameter incorporated in the presently rejected claims would have been obvious in light of Anderson et al. They exhibit separate features of the combination of high compliance and high wall strength for specifically sized balloons, as well as high burst pressures, which in fact are not suggested in the prior art or previously attainable.

Claims 44-45 are also directed toward larger balloons and are similarly not obvious for the reasons stated above with regard to claims 38-39.

(5)

Claim 43 was rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. in view of Kaneko et al. (USPN 5344400). It is asserted that Anderson et al. discloses the invention substantially as claimed except for the balloon being formed from at least two concentric layers of different thermoplastic polymers. However, it is asserted, Kaneko et al. teaches a balloon having the missing limitation, and that it would have been obvious to combine the two reference making claim 43 obvious.

The rejection fails because there is no indicated teaching or motivation to make the combination. There is no indication in the references that the combination would work as intended in Anderson et al. The teachings of Anderson et al. clearly indicate that the specific materials (see col.7, line 48, through col 8, line 60), which incorporate a series of "hard" and "soft" segments which can coil upon themselves, the heat set step and the sterilization step work together to produce the final product with specific physical characteristics. Kaneko et al. teaches a balloon which is produced by molding polyarylenesulfide or an alloy thereof, wherein polyarylenesulfide is a main constituent. The rejection is based on the disclosure relating to the three layer embodiment in figure 3 and described starting at col. 6, line 54. This embodiment describes a layered balloon wherein a layer of PAS and a layer of polyolefin are adhered to each other via a layer of a non-uniform two-component layer of a blend of PAS and polyolefin. The components of the three layered embodiment are detailed and specific to the invention. There is no indication or teaching in Kaneko et al. that would lead one to add an extra layer of a separate thermoplastic material to the balloon of Anderson et al. There is no indication that the material or the three layers suggested by Kaneko et al. would behave similarly to the balloons of Anderson et al or be compatible with the Anderson et al. materials or method steps. It is impossible to determine. As such, there is no motivation to make the combination suggested in the rejection.

Further, one of the main intents of Anderson et al. is improved distensibility. The additions of layers would frustrate this purpose. Having the further layers would have an unknown effect on the balloon of Anderson et al. There is no guidance in the references as why adding the extra layers would be desirable or compatible. The combination of references offers no ideas regarding the variations beyond the exact parameters. As such, the combination fails to make the claims obvious. Reversal of the rejection is therefore requested.

(6)

Claims 46 and 47 were rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. in view of U.S. Patent No. 5,167,239 to Cohen et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose a method of treating a gastrointestinal lesion having the steps as claimed by Applicant. However, it is asserted that Cohen et al. teaches a device having the missing limitation, and that it would have been obvious to combine the two reference making claims 46 and 47 obvious.

Claims 46-47 are also directed toward larger balloons and are similarly not obvious for the reasons stated above with regard to claims 38-39. Balloons for the gastrointestinal tract are quite large and aren't contemplated in Anderson et al. There is no indication of how the expected parameters of Anderson et al. might be effected in a large balloon.

Further, Cohen et al. dicloses a different device for a different purpose. The Cohen device is an anchorable guidewire. The balloon portion is quite different from that of Anderson et al. The Anderson et al. balloon is a angioplasty balloon. Such balloons require a greater degree of control in expansion. The balloons of Cohen expand with a great degree of elongation. In fact, the elongation of a prefered material is upwords of 900 (see col. 12, lines 5-8). The elongation is important because it is preferable that the outer diameter of the balloon, when fully deflated and unstretched state, be approximately the same as, or smaller than, the outer diameter of the guidewire body. High elongation is needed in order to go from that very low profile state to an expanded state large enough to perform the anchoring task. The balloons

of Anderson et al. are not taught with this amount of elongation. It isn't needed for the purpose for which the angioplasty catheters serve. Angioplasy balloons are typically folded and have a limited expansion with significant control. As such, there is no motivation to make the combination. As mentioned above, Anderson et al. does not discuss balloons of this size. Merely combining Anderson et al. with a reference which discusses balloons used in gastrointestinal procedures is not enough to sustain the rejection. Anderson et al. discloses a specific type of balloon, having specific parameters, for a specific function. Cohen teachs a different type of balloon, having different parameters, for a different function. Motivation to combine, as well as an articulation of a workable combination, are lacking. Reversal of the rejection is requested.

CONCLUSION

In light of the above comments and the previously filed Appeal Brief and Reply Brief, the rejection of claim 11 under 35 U.S.C. §102 and of claims 12-17, 37-39 and 43-47 under 35 U.S.C. §103(a) must be reversed as being erroneous. It is respectfully requested that the Board of Patent Appeals and Interferences reverse all of the outstanding rejections and pass the application to issue.

Respectfully submitted,

VIDAS ARRETT & STEINKRAUS

Dated: May 16, 2001

William E. Anderson II
Attorney Reg. 37,766

Suite 2000
6109 Blue Circle Drive
Minnetonka, MN 55343-9131
Phone: (612) 563-3000
Facsimile: (612) 563-3001
F:\WPWORK\WEA\5902-BRF.511